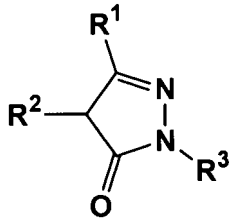
Amendments to the Claims

1. (Currently Amended) A method for treating amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or suppressing the progression thereof, which comprises administering to a patient in need thereof as an active ingredient a pyrazolone derivative represented by the following formula (I) or a physiologically acceptable salt thereof, or a hydrate thereof or a solvate thereof:

[Chem.1]



(I)

wherein R^1 represents a hydrogen atom, aryl, C_{1-5} alkyl, or C_{3-6} (total carbon number) alkoxycarbonylalkyl, R^2 represents a hydrogen atom, aryloxy, arylthio, C_{1-5} alkyl or C_{1-3} hydroxyalkyl, or R^1 and R^2 are combined with each other to represent C_{3-5} alkylene group, and R^3 represents a hydrogen atom, C_{1-5} alkyl, C_{5-7} cycloalkyl, C_{1-3} hydroxyalkyl, benzyl, naphthyl or phenyl, or phenyl substituted with the same or different 1 to 3 substituents selected from the group consisting of C_{1-5} alkoxy, C_{1-3} hydroxyalkyl, C_{2-5} (total carbon number) alkoxycarbonyl, C_{1-3} alkylthio, C_{1-4} alkylamino, C_{2-8} (total carbon number) dialkylamino, halogen atom, trifluoromethyl, carboxyl, cyano, hydroxyl group, nitro, amino and acetamide, under the condition that a drug holiday period of 1 day or more is provided ~~once or twice~~ once, twice or more during the period for treating the disease or suppressing the progression of the disease.

2. (Previously presented) The method of claim 1, wherein the pyrazolone derivative is 3-methyl-1-phenyl-2-pyrazoline-5-on.

3. (Previously presented) The method of claim 1, wherein the drug holiday period is provided after a drug administration period of about 7 to 14 days.

4. (Previously presented) The method of claim 1, wherein a second or subsequent drug administration period is about 5 to 14 days.

5. (Previously presented) The method of claim 1, wherein the drug holiday period is about 14 to 16 days.

6. (Previously presented) The method of claim 1, wherein the drug administration period and the drug holiday period are each 14 days.

7. (Previously presented) The method of claim 1, wherein a course consisting of an initial drug administration period of 14 days and a drug holiday period of 14 days is provided, followed by repetitions of the following combination of periods:

drug administration period: 5 days per week for 2 weeks; and

drug holiday period: 14 days.

8. (Previously presented) The method of claim 1, wherein the daily dose contains about 15 to 240 mg of a pyrazolone derivative as an active ingredient, or about 15 to 240 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

9. (Previously presented) The method of claim 1, wherein the daily dose contains about 60 mg of a pyrazolone derivative as an active ingredient, or about 60 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

10. (Previously presented) The method of claim 1, wherein the administration is carried out once daily.

11. (Previously presented) The method of claim 1, wherein the administration is a continuous administration.

12. (Previously presented) The method of claim 11, wherein the continuous administration is intravenous infusion administration.

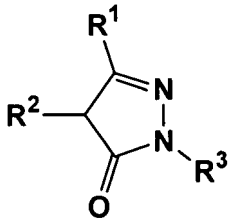
13. (Previously presented) The method of claim 12, wherein the administration rate in the intravenous infusion administration is about 0.5 to 1 mg/minute with respect to a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient.

14. (Previously presented) The method of claim 11, wherein the continuous administration is an administration form that is substantially equivalent to the intravenous infusion administration wherein the amount of a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient administered per minute is about 0.5 to 1 mg.

15. (Previously presented) The method of claim 1 wherein the symptoms caused by amyotrophic lateral sclerosis are decreased respiratory function, voice and speech disorders, dysphagia, or upper and lower extremity motor disorders.

16. (Previously presented) The method of claim 1 wherein the treatment of amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or the suppression of the progression thereof is a suppression of decrease in respiratory function in amyotrophic lateral sclerosis.

17. (Original) A method for administrating as an active ingredient a pyrazolone derivative represented by the following formula (I) or a physiologically acceptable salt thereof, or a hydrate thereof or a solvate thereof, for treating amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or suppressing the progression thereof, wherein a drug holiday period of 1 day or more is provided once or twice during the period for treating the disease or suppressing the progression of the disease,
[Chem.2]



(I)

wherein R^1 represents a hydrogen atom, aryl, C_{1-5} alkyl, or C_{3-6} (total carbon number) alkoxycarbonylalkyl, R^2 represents a hydrogen atom, aryloxy, arylthio, C_{1-5} alkyl or C_{1-3} hydroxyalkyl, or R^1 and R^2 are combined with each other to represent C_{3-5} alkylene group, and R^3 represents a hydrogen atom, C_{1-5} alkyl, C_{5-7} cycloalkyl, C_{1-3} hydroxyalkyl, benzyl, naphthyl or phenyl, or phenyl substituted with the same or different 1 to 3 substituents selected from the group consisting of C_{1-5} alkoxy, C_{1-3} hydroxyalkyl, C_{2-5} (total carbon number) alkoxycarbonyl, C_{1-3} alkylthio, C_{1-4} alkylamino, C_{2-8} (total carbon number) dialkylamino, halogen atom, trifluoromethyl, carboxyl, cyano, hydroxyl group, nitro, amino and acetamide.

18. (Original) The method for administration of claim 17, wherein the pyrazolone derivative is 3-methyl-1-phenyl-2-pyrazoline-5-on.

19. (Previously presented) The method for administration of claim 17, wherein the drug holiday period is provided after a drug administration period of about 7 to 14 days.

20. (Previously presented) The method for administration of claim 17, wherein a second or subsequent drug administration period is about 5 to 14 days.

21. (Previously presented) The method for administration of claim 17, wherein the drug holiday period is about 14 to 16 days.

22. (Previously presented) The method for administration of claim 17, wherein the drug administration period and the drug holiday period are each 14 days.

23. (Previously presented) The method for administration of claim 17, wherein a course consisting of an initial drug administration period of 14 days and a drug holiday period of 14 days is provided, followed by repetitions of the following combination of periods:

drug administration period: 5 days per week for 2 weeks; and
drug holiday period: 14 days.

24. (Previously presented) The method for administration of claim 17, wherein the daily dose contains about 15 to 240 mg of a pyrazolone derivative as an active ingredient, or about 15 to 240 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

25. (Previously presented) The method for administration of claim 17, wherein the daily dose contains about 60 mg of a pyrazolone derivative as an active ingredient, or about 60 mg of a pyrazolone derivative contained in a pharmaceutically acceptable salt of a pyrazolone derivative or a hydrate or solvate of a pyrazolone derivative or a pharmaceutically acceptable salt thereof as an active ingredient.

26. (Previously presented) The method for administration of claim 17, wherein the administration is carried out once daily.

27. (Previously presented) The method for administration of claim 17, wherein the administration is a continuous administration.

28. (Original) The method for administration of claim 27, wherein the continuous administration is intravenous infusion administration.

29. (Original) The method for administration of claim 28, wherein the administration rate in the intravenous infusion administration is about 0.5 to 1 mg/minute with respect to a pyrazolone derivative as an active ingredient or a pyrazolone derivative contained in an active ingredient.

30. (Original) The method for administration of claim 27, wherein the continuous administration is an administration form that is substantially equivalent to the intravenous infusion administration wherein the amount of a pyrazolone derivative as an active ingredient or a

pyrazolone derivative contained in an active ingredient administered per minute is about 0.5 to 1 mg.

31. (Previously presented) The method for administration of claim 17 wherein the symptoms caused by amyotrophic lateral sclerosis are decreased respiratory function, voice and speech disorders, dysphagia, or upper and lower extremity motor disorders.

32. (Previously presented) The method for administration of claim 17 wherein the treatment of amyotrophic lateral sclerosis or symptoms caused by amyotrophic lateral sclerosis and/or the suppression of the progression thereof is a suppression of decrease in respiratory function in amyotrophic lateral sclerosis.